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FEDERAL CONTROL IN THE FOOD AND DRUG INDUSTRIES

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INTRODUCTION

If the attention or lack of attention law reviews give to a subject is indicative of the amount of governmental control therein, then one would conclude that there is little federal regulation in the food and drug fields.¹ The fact is, however, that there are more than 1,200 pages of federal statutes and administrative regulations affecting the food and drug industries, and no industry is more tightly controlled. The antitrust, securities, and labor statutes, for example, are, if anything, less stringent.

In the main, the approach of food and drug regulation is from a different point of view than that of many governmental controls of business. The Sherman Antitrust Act, the various financial and banking acts, important aspects of the Federal Trade Commission Act, and many others are concerned with business practices. Is this a restraint of trade; is this monopoly power; is this an unfair method of competition? The Sherman Act is a statute to help business, to make competition work, to promote the success of the capitalistic theory. With some exceptions,² food and drug controls are aimed primarily at the protection of the consumer. Is this product adulterated? Is this drug safe? Is it properly labeled? The accent is on both health and economics—from the consumer's viewpoint.

This consumer-protection approach results in tough regulation of business. For example, the food and drug producer frequently is held to strict or absolute liability under a criminal statute; intent and knowledge are not material.

HISTORY OF FEDERAL REGULATION

The states have had some regulation of food and drug industries since colonial days, and they began to enact general food and drug laws after 1870, Illinois being the first. Broad federal controls are

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1. Only two law journals have spotlighted these controls: *Developments in the Law: The Federal Food, Drug, and Cosmetics Act*, 67 HARV. L. REV. 632 (1954); *Symposium, The New Food, Drug, and Cosmetic Legislation*, 6 LAW & CONTEMP. PROB. 1-182 (1939); *Symposium, The Protection of the Consumer of Food and Drugs*, 1 LAW & CONTEMP. PROB. 1-133 (1934).

2. One exception to this statement is the Packers and Stockyards Act of 1921, 42 STAT. 159, as amended, 7 U.S.C. §§ 181-229 (1952).

creatures of the twentieth century.³ In 1906, the first comprehensive food and drug law⁴ and the first effective meat inspection act⁵ were enacted, and these two acts, with some changes, are still the heart of the federal regulation of the industries. Earlier, there had been relatively weak federal controls over exports and imports⁶ and also meats,⁷ and Congress had passed quite strict laws regarding such items as oleomargarine and filled cheese.⁸

THE MEAT INDUSTRY

Meat Inspection Act: In 1906, the country was shocked by revelations concerning the meat packing-houses. A novel by Upton Sinclair,⁹ articles in magazines, and government reports made public by President Theodore Roosevelt¹⁰ revealed conditions in the industry, involving such things as lack of sanitation, use of unsafe preservatives, and the sale of diseased and decayed meat, which caused an uproar among the citizenry and led to the enactment by Congress¹¹ of a strong meat inspection law.¹² With minor amendments, this statute is still in force.

The goal of this legislation is to keep unfit meat out of interstate commerce. The device used is inspection of all meat prior to shipment.¹³ Thus, only inspected meat may move in interstate commerce.

If a packer desires to ship interstate, he applies for inspection. He is then informed by the Department of Agriculture, which administers this law, what plant and inspection facilities must be available before inspection will be inaugurated. Thus, the Department has basic requirements as to the physical facilities which a packer must have. These include space and facilities for the government inspectors as well as general plant facilities for proper sanitation and the like.¹⁴ A packer meets these requirements or he doesn't get inspected.¹⁵

The meat is under the constant surveillance of the government inspectors. They examine the live animals, the slaughtered animals,

3. See 3 ENCYC. SOC. SCI. 297 (1931). The early statutes in Europe and in the United States were largely economic ones (weights and measures, water in milk, and the like). Today, health is the main motive, although economic aspects are often important.

4. 34 STAT. 768 (1906).

5. 34 STAT. 674, 1260 (1906, 1907), 21 U.S.C. §§ 71-91 (1952).

6. See, e.g., 9 STAT. 237 (1848), 26 STAT. 414 (1890).

7. 26 STAT. 1089 (1891).

8. 24 STAT. 209 (1886) (oleomargarine); 29 STAT. 253 (1896) (filled cheese).

9. THE JUNGLE (1905).

10. See SULLIVAN, OUR TIMES (AMERICA FINDING HERSELF) 536-37 (1927).

11. For background, see *id.* at 535-50.

12. 34 STAT. 1260 (1907), as amended, 21 U.S.C. §§ 71-91 (1952).

13. It may be observed that Congress has available two approaches for an act such as this. One is the inspection of the product before shipment; this is the one used here. The other is a prohibition against shipping a prohibited product (i.e., an adulterated or misbranded item), with a penalty, civil or criminal, for violation. The second approach is used in the Federal Food, Drug, and Cosmetic Act, discussed in the section *infra* dealing with the food industry.

14. 9 C.F.R. §§ 7.1-8.15 (1949).

15. Shipment interstate of uninspected meat is a misdemeanor. 34 STAT. 1264 (1907), 21 U.S.C. § 88 (1952).

the carcasses, the cut-up meat, the meat product; they oversee the destruction of any meat condemned for disease.

Each plant thus has inspectors stationed therein who watch all the time. At the end, each piece of meat which passes inspection must be stamped by the government official as "U.S. Inspected and Passed."

The inspectors are authorized to enter and inspect a plant at any time, day or night or holiday.¹⁶ This right of inspection exceeds in scope and authority that of most other federal inspection laws.

The Secretary of Agriculture also is authorized to promulgate standards of identity for meat products (what goes in the product). Hamburger is an example. Sausage is another; the Secretary limits the amount of cereal and water that may be added to this product.¹⁷ Labeling is controlled, and even the use of a trademark may be prohibited as being misleading.¹⁸ The label must be both honest and informative; if the over-all impression on the consumer may be misleading, literal truthfulness of the label will not save it.

Thus, federal control over the meat-packing industry, as to the physical plant and its operation and as to the meat, is as complete and absolute as it is possible to make it.¹⁹

When the act was introduced in 1906, the packers opposed it with every means at their command,²⁰ but today no voice is raised in public against these controls, and the packers look on them not only as protection for the consumer but as a guardian against unfair competition from unscrupulous producers.

Poultry Products Inspection Act: Poultry is not covered by the Meat Inspection Act. However, a 1957 congressional act provides for compulsory inspection by the Department of Agriculture of poultry and poultry products²¹ intended for or affecting interstate commerce, the act to be effective on January 1, 1959.

Packers and Stockyards Act of 1921: The Packers and Stockyards Act²² regulates the business practices of meat packers, stockyards, and live poultry dealers. It combines many of the provisions of the Sherman,²³ Federal Trade Commission,²⁴ Clayton,²⁵ and Robinson-Patman²⁶

16. 34 STAT. 1261 (1907), 21 U.S.C. § 74 (1952).

17. 9 C.F.R. § 18.7 (1949).

18. Examples of control over ingredients and labeling are: liver sausage, ham spread, potted meat, pork sausage, scrapple, spaghetti sauce with meat, chili con carne, hash, tamales, corned beef. If these terms are used on the label, the product must conform to the Department's requirements as to ingredients.

19. The Government bears the ordinary expenses of such inspections. The packer pays if overtime, holidays, or week ends are involved.

20. See SULLIVAN, *op. cit. supra* note 10, at 538-43.

21. Pub. L. No. 85-172, 85th Cong., 1st Sess. (Aug. 28, 1957).

22. 42 STAT. 159, as amended, 7 U.S.C. §§ 181-229 (1952).

23. 26 STAT. 209 (1890), as amended, 15 U.S.C. §§ 1-8 (1952).

24. 38 STAT. 717 (1914), as amended, 15 U.S.C. §§ 41-51 (1952).

25. 38 STAT. 730 (1914), as amended, 15 U.S.C. §§ 12-27 (1952).

26. 49 STAT. 1526 (1936), 15 U.S.C. §§ 13, 13(a)-(b) (1952).

acts. It authorizes the Secretary of Agriculture to enforce its provisions.²⁷ The regulation is broad in coverage. Forbidden are: (1) unfair, unjustly discriminatory, or deceptive practices; (2) the making or giving of any undue or unreasonable preference or advantage to any particular person or locality; (3) acts which have the effect of apportioning the market; (4) selling or any other act for purpose of controlling prices, or of securing a monopoly.²⁸

Stockyards are required to furnish services without discrimination and to charge reasonable and nondiscriminatory rates, such rates to be available for public inspection.²⁹ To be covered by this act, the stockyard itself does not have to be engaged in interstate commerce; the requirement is that the cattle, etc., using the yard be in commerce.³⁰ This coverage gave rise to one of the classic commerce power decisions, in which Chief Justice Taft spoke of the stockyards as "a throat through which the current flows."³¹

Since the Federal Trade Commission is ousted from control,³² an interesting jurisdictional question sometimes arises between the FTC and the Department of Agriculture. When Corporation X owns a packing plant and also a plant producing, say, steel ball-bearings, who has jurisdiction as to unfair practices in the ball-bearing plant? Recent FTC decisions hold that the Department of Agriculture has jurisdiction in such a case.³³ This holding can only lead to confusion and injustice, for it is apparent that the Department of Agriculture is not equipped to handle charges against a ball-bearing producer. Legislation probably will be required to solve the problem.

THE FOOD INDUSTRY³⁴

Federal Food, Drug, and Cosmetic Act: The primary national statute in the food field is the Federal Food, Drug, and Cosmetic Act.³⁵ In

27. The Sherman Act still applies to the industry, but the Federal Trade Commission has "no power or jurisdiction so far as relating to any matter which by this Act is made subject to the jurisdiction of the Secretary" Packers and Stockyards Act §§ 405-06, 7 U.S.C. §§ 225-27 (1952). This means that an unfair or deceptive practice charge against a packer, stockyard, or live poultry dealer is heard by the Department of Agriculture, not by the Federal Trade Commission. See *United Corporation v. FTC*, 110 F.2d 473 (4th Cir. 1940).

28. 42 STAT. 161 (1921), as amended, 7 U.S.C. § 192 (1952).

29. 42 STAT. 164, 165 (1921), as amended, 7 U.S.C. §§ 205-208 (1952).

30. 42 STAT. 163 (1921), 7 U.S.C. § 202 (1952).

31. *Stafford v. Wallace*, 258 U.S. 495, 516 (1922).

32. See note 27 *supra*.

33. *Food Fair Stores, Inc.*, CCH TRADE REG. REP. (1957 Trade Cas.) ¶ 26729 at 36345 (Initial order, Apr. 18, 1957); *Giant Food Shopping Center*, CCH TRADE REG. REP. (1957 Trade Cas.) ¶ 26645 at 36299 (Initial order, Aug. 15, 1957). In the writer's opinion, these holdings are in error, but unless the FTC itself changes the ruling, there is no way to get a court decision.

34. The meat packing industry is excluded from this section, having been discussed in the preceding section.

35. 52 STAT. 1041 (1938), as amended, 21 U.S.C. §§ 301-92 (1952). The

general, the statute prohibits in interstate commerce goods which are adulterated or misbranded. The terms "adulterated" and "misbranded" are defined in the act, and they are both quite broad in their coverage. For example, a food produced in a filthy plant is "adulterated" whether or not the product is found to be contaminated with the filth.³⁶ Omitting a valuable constituent, or concealing damage or inferiority constitute adulteration.³⁷

Misbranding applies to the labeling. The label must not be misleading or false "in any particular;" the label must so state if the product is an imitation; the container must not be misleading; the label must give certain information, such as name and address of producer, quantity of contents, and in certain cases the ingredients.³⁸

The act also provides for the promulgation of food standards, and such standards are mandatory on the interstate producer.³⁹ There are three types of standards under this provision: identity, quality, and fill of container. The standard of identity for canned tomatoes, for example, sets out what ingredients may be used in making the product, and it is thus a sort of recipe. The standard of quality for canned tomatoes sets up the minimum requirements of quality; these include maximum amounts allowed of peel, blemishes, and the like. The standard of fill of container specifies how full the bottle or can must be. The interstate producer of canned tomatoes thus must comply with detailed federal specifications.

Unlike the Meat Inspection Act, this statute uses the "catch the offender" method of enforcement.⁴⁰ There are three procedures regarding violations, namely, seizure of the product, criminal prosecution, and injunction.⁴¹ The first two are commonly used, the last rarely.

In a criminal proceeding, intent and knowledge are not parts of the proof. Thus, a form of absolute criminal liability is imposed on management, a fact that may be startling to the criminal lawyer. The producer of food (or drugs or cosmetics) assumes the risk and must put out a product which is legally good. It thus is apparent that the

1906 Act (see note 4 *supra*) was replaced by the 1938 Act. The Act is enforced by the Food and Drug Administration, which is under the Department of Health, Education, and Welfare.

36. "A food shall be deemed to be adulterated . . . (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health" 52 STAT. 1046 (1938), as amended, 21 U.S.C. § 342(a) (1952).

37. 52 STAT. 1046 (1938), as amended, 21 U.S.C. § 342 (1952).

38. 52 STAT. 1047 (1938), as amended, 21 U.S.C. § 343 (1952).

39. 52 STAT. 1046 (1938), as amended, 21 U.S.C. § 341 (1952).

40. The act also provides for factory and plant inspection, but on a "spot" check basis; thus, inspection is not a prerequisite for shipment. It should also be said that this inspection is used not only to catch the violators but to encourage compliance voluntarily. 52 STAT. 1057 (1938), as amended, 21 U.S.C. § 374 (1952).

41. 52 STAT. 1043, 1044 (1938), as amended, 21 U.S.C. §§ 332-34 (1952).

fundamental objective of this statute is the protection of the consumer.⁴² To insure the welfare of the consumer, the food (and drug and cosmetic) producer operates under one of the strictest criminal laws, and, it is interesting to note, this criminal statute is given a liberal, not a strict, interpretation.⁴³

Strict as the law is, among the warmest supporters thereof are food producers themselves. One of the reasons for this is that the statute promotes fair competition and enables an honest manufacturer to compete in the market. Another reason is the good sense that the Food and Drug Administration has used through the years in administering the law. The FDA is strict, but it is fair, and it works with the industry on problems; its goal is compliance, achieved, where feasible, through education and cooperation. Students of administrative law would do well to study the FDA, an agency which has used a strict statute to give every possible protection to the consumer, and yet one which has kept the respect of the regulated industry. There are few parallels in government.

Other Food Laws: There are many other statutes that regulate the food industry. The Department of Agriculture is authorized to set up grades for foods (and for grain), and these are used on a *voluntary* basis by producers.⁴⁴ The "Grade A," "Grade B," etc., one sees on products come from this statute. There are regulations for filled cheese,⁴⁵ filled milk,⁴⁶ oleomargarine,⁴⁷ renovated butter,⁴⁸ apples and pears,⁴⁹ and imported milk.⁵⁰ Also, there are very strict controls over the importation of tea.⁵¹ The latter statute delegates to an administrative agency broad, almost complete, power over imported tea, and authorizes it to regulate by what amounts to subjective standards. For example, one part of the testing really is this: Does the tea taste good?⁵²

There are more than forty other statutes, not the least of which are the weights and measures acts.⁵³

42. See *United States v. Dotterweich*, 320 U.S. 277 (1943).

43. *Ibid.*

44. 60 STAT. 1087 (1946), 7 U.S.C. §§ 1621-29 (1952). Grain standards are provided for in 39 STAT. 482 (1916), as amended, 7 U.S.C. §§ 71-87 (1952).

45. INT. REV. CODE OF 1954, §§ 4831-46, 7236, 7266, 7303, 7641.

46. 42 STAT. 1486 (1923), as amended, 21 U.S.C. §§ 61-64 (1952).

47. The bulk of this regulation is in the Federal Food, Drug, and Cosmetic Act, §§ 402(e), 407, 52 STAT. 1040, 21 U.S.C. 301 (1952). Also, see INT. REV. CODE OF 1954, §§ 4591-97, 7234, 7265, 7303, 7641.

48. INT. REV. CODE OF 1954, §§ 4811-26, 7234-35, 7641.

49. 48 STAT. 123 (1933), 7 U.S.C. §§ 581-89 (1952); 37 STAT. 250 (1912), 21 U.S.C. §§ 20-23 (1952).

50. 44 STAT. 1101 (1927), as amended, 21 U.S.C. §§ 141-49 (1952).

51. 29 STAT. 604 (1897), as amended, 21 U.S.C. §§ 41-50 (1952).

52. See *Buttfield v. Stranahan*, 192 U.S. 470 (1904); *Buttfield v. Bidwell*, 96 Fed. 328 (2d Cir. 1899).

53. See CHRISTOPHER AND DUNN, *SPECIAL FEDERAL FOOD AND DRUG LAWS* (1954).

THE DRUG INDUSTRY

Narcotics: There are three narcotic acts of importance. Besides the Harrison Act,⁵⁴ there is the Opium Poppy Control Act of 1942⁵⁵ and the Narcotic Drugs Import and Export Act.⁵⁶ These statutes impose exact and severe regulations on the production and sale of narcotics. State statutes also are important in this field.

Since the national government has no "police power" as such, these statutes provide examples of how Congress can outlaw a product and regulate an industry. The Harrison Act is based on the taxing power, the Poppy Control Act on the treaty power, and the Import and Export Act on the power to regulate commerce with foreign nations.

Drugs: The Federal Food, Drug, and Cosmetic Act⁵⁷ prohibits adulteration and misbranding of drugs in a similar fashion to the regulation of food. Standards are set up for drugs, based on official compendiums,⁵⁸ and exacting requirements are provided in regard to prescription drugs.⁵⁹ A new drug cannot be marketed until the producer satisfies the Food and Drug Administration that the product is safe, a requirement that is of great importance in this era of new drugs. Certain items, such as insulin, penicillin, and other "wonder" drugs are tested by the government, batch by batch, before sale. Coal-tar colors used in drugs (or in foods or cosmetics) must be certified by the FDA, and this agency is authorized to proscribe the use of unsafe colors.⁶⁰

Other federal acts regulate the production of biologic products such as serums and toxins⁶¹ as well as caustic poisons,⁶² insecticides,⁶³ industrial alcohol,⁶⁴ and naval stores.⁶⁵

54. INT. REV. CODE OF 1954, §§ 4701-75, 7237-38.

55. 56 STAT. 1045, 21 U.S.C. §§ 188(a)-(n) (1952).

56. 35 STAT. 614 (1909), as amended, 21 U.S.C. §§ 171-74, 176-85 (1952).

57. 52 STAT. 1041 (1938), as amended, 21 U.S.C. §§ 301-92 (1952).

58. 21 U.S.C. § 352(g).

59. 21 U.S.C. § 353(b).

60. A recent order deleted three coal-tar colors from the list approved for certification for use. 20 FED. REG. 8492 (1955). Petitions for review of that order were filed in three circuits. The petition filed in the seventh circuit was dismissed. The order was affirmed in the second circuit. *Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 236 F.2d 866 (2d Cir. 1956). But in a two to one decision, the fifth circuit has reversed the order. *Florida Citrus Exchange v. Folsom*, 246 F.2d 850 (5th Cir. 1957). The position of the majority in the fifth circuit is that, even though consumption of large quantities of the color is unsafe, there must be a finding as to the likelihood of injury to the health of persons who consume food to which a small quantity of the color has been added.

61. 58 STAT. 702 (1944), 42 U.S.C. §§ 262-63 (1952); 37 STAT. 832 (1913), 21 U.S.C. §§ 151-58 (1952).

62. 44 STAT. 1406 (1927), 15 U.S.C. §§ 401-11 (1952).

63. 61 STAT. 163 (1947), 7 U.S.C. §§ 135(a)-(k) (1952).

64. INT. REV. CODE OF 1954, §§ 5301-20, 5331-34.

65. 42 STAT. 1435 (1923), 7 U.S.C. §§ 91-99 (1952).

CONCLUSION

These food and drug statutes are strict and complex. They are aimed, in the main, at consumer protection. In the words of Mr. Justice Frankfurter, speaking of the Food and Drug Act, "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation . . ."⁶⁶

In 1956, the American people consumed \$73,000,000,000 worth of food,⁶⁷ of which amount about half was bought in grocery stores. We live out of cans and packages. A large percentage of the drugs used by doctors today was not even on the market twenty years ago. Each year, thousands of lives depend on the drug used being of the proper strength and purity, and some of these products require the most exacting procedures in manufacture. It thus is evident that the regulation in the food and drug fields, extensive and strict as it is, is among the fundamental commercial laws in the land.

Nothing has been said about the need for changes or for additional laws, as these are not within the scope of this paper. But it should be stated that these regulations are not perfect. On the federal level, one of the needs is for stronger advertising laws. Another is for an adequate statute regulating exported food and drugs. A third is for reasonable regulation in the relatively new field of chemicals to be added to foods. Some of the agencies are restricted due to inadequate appropriations by Congress—the Food and Drug Administration is an example. And there are others. On the state level, the needs are many. Some states need better laws; most states, probably, need better enforcement. Some states have very strict laws and enforcement regarding seeds and fertilizer for farmers and for dog and cattle feed, and weak laws or enforcement regarding food and drugs for humans.

One of the more pressing needs is for education among judges and enforcement officials. Food and drug officials frequently complain that it does no good to catch a violator. It is rumored that one inspector lost his job for finding rats in a food plant. This education can be carried on by newspapers, which, by and large, have ignored food and drug laws and by law reviews and law schools. Strangely enough, the food and drug industries themselves have worked hard at educating the public regarding these laws.

Educate and inform we must, for these regulations are essential to the national well being.

66. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

67. 25 *FOOD FIELD REPORTER* (No. 18) p. 12, cols. 1, 2, 3, 4 (Sept. 2, 1957).